



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers treatment of tinnitus with ANY of the following therapies to be **investigational***:

- Biofeedback; OR
- Tinnitus maskers, customized sound therapy; OR
- Combined psychological and sound therapy (eg, tinnitus retraining therapy) ; OR
- Transcranial magnetic stimulation; OR
- Transcranial direct current stimulation; OR
- Electrical transcutaneous electrical stimulation of the ear, electromagnetic energy; OR
- Transmeatal laser irradiation.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Note: This policy does not address surgical (eg, cochlear or brainstem implant), pharmacologic treatment of tinnitus, (e.g., the use of amitriptyline or other tricyclic antidepressants), or injection of botulinum toxin.

Background/Overview

Tinnitus

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective types. The latter describes the minority of cases, in which an external stimulus is potentially heard by an observer (eg, by placing a stethoscope over the patient's external ear). Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. The more common type is subjective tinnitus, which is frequently self-limited. In a small subset of patients with subjective tinnitus, its intensity and persistence leads to disruption of daily life. While many patients habituate to tinnitus, others may seek medical care if the tinnitus becomes too disruptive.

Many treatments are supportive because currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on the use of devices worn in the ear that produce a broad band of continuous external noise that drowns out or masks the tinnitus. Psychological therapies may also be provided to improve coping skills, typically requiring 4 to 6 one-hour visits over an 18-month period. Tinnitus retraining therapy, also referred to as tinnitus habituation therapy, is based on the theories of Jastreboff, who proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor in some patients' unpleasant response to the noise is due to a spreading of the signal and an abnormal conditioned reflex in the extra-auditory limbic and autonomic nervous systems. The goal of tinnitus retraining therapy is to habituate (retrain) the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus but is set at a level such that the tinnitus can still be detected. This strategy is thought to enhance extinction of the subconsciously conditioned reflexes connecting the auditory system with the limbic and autonomic nervous systems by increasing neuronal activity within the auditory system. Treatment may also include the use of hearing aids to increase external auditory stimulation. The Heidelberg model uses an intensive

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

program of active and receptive music therapy, relaxation with habituation to the tinnitus sound, and stress mapping with a therapist.

Sound therapy is a treatment approach based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment) prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual patient's hearing thresholds. This is achieved by boosting the amplitude of those frequencies at which an audiogram has shown the patient to have a reduced hearing threshold. Also being evaluated is auditory tone discrimination training at or around the tinnitus frequency. Another type of sound therapy being investigated uses music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex. One theory behind the notched music is that tinnitus is triggered by injury to inner ear hair cell population, resulting in both a loss of excitatory stimulation of the represented auditory cortex and loss of inhibition on the adjoining frequency areas. It is proposed that this loss of inhibition leads to hyperactivity and overrepresentation at the edge of the damaged frequency areas and that removing the frequencies overrepresented at the audiometric edge will result in the reorganization of the brain.

Electrical stimulation to the external ear has also been investigated and is based on the observation that electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transcranial magnetic stimulation, electrical stimulation, and transmeatal low-power laser irradiation have also been evaluated.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The Neuromonics[®] Tinnitus Treatment is one of many tinnitus maskers cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. It is "...intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system." FDA product code: KLW.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Table 1. Devices Cleared by the U.S. Food and Drug Administration

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
Multiflex Tinnitus Technology	Starkey Laboratories	6/19/2020	K201370	Tinnitus Relief
Tinnitus Sound Generator Module	Gn Hearing A/S	2/20/2020	K193303	Tinnitus Relief
Tinnitus Sound Generator Module	Gn Hearing A/S	11/30/2018	K180495	Tinnitus Relief
Audifon Tinnitus-Module	Audiofon Usa Inc.	10/19/2017	K171243	Tinnitus Relief
Tinnilogic Mobile Tinnitus Management De	Jiangsu Betterlife Medical Co., Ltd.	5/17/2017	K163094	Tinnitus Relief
Sound Options Tinnitus Treatment	Sound Options Tinnitus Treatments Inc.	9/28/2016	K161562	Tinnitus Relief
Hypersound Tinnitus Module	Turtle Beach Corporation	8/23/2016	K161331	Tinnitus Relief
Desyncra For Tinnitus Therapy System, De	Neurotherapies Reset Gmbh.	1/20/2016	K151558	Tinnitus Relief
Reve134	Kw Ear Lab, Inc	10/9/2015	K151719	Tinnitus Relief
Serenity	Sanuthera, Inc.	7/27/2015	K150014	Tinnitus Relief
Soundcure Serenade Tinnitus Treatment Sy	Soundcure, Inc.	4/13/2015	K150065	Tinnitus Relief

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Levo Tinnitus Masking Software Device	Otoharmonics Corp	7/18/2014	K140845	Tinnitus Relief
Solace Sound Generators	Amplisound Hearing Products & Services	3/25/2014	K132965	Tinnitus Relief
Tinnitus Sound support	Oticon A/S	3/18/2014	K133308	Tinnitus Relief
Wave 2g, Soul	Hansaton Akustik Gmbh	1/3/2014	K130937	Tinnitus Relief

Rationale/Source

Description

Various nonpharmacologic treatments are being evaluated to improve the symptoms of tinnitus. These approaches include psychological coping therapies, sound therapies, combined psychological and sound therapies, repetitive transcranial magnetic stimulation, electrical and electromagnetic stimulation, and transmeatal laser irradiation.

Summary of Evidence

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of cognitive and behavioral therapies have found improvements in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs have reported that a self-help/Internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy may also improve coping skills. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have tinnitus who receive sound therapy, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus masking includes RCTs and a systematic review of RCTs. The RCTs had medium- to high-risk of bias and did not show the efficacy of

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described the use of very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch. A 2016 trial, double-blinded and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. A benefit on tinnitus loudness but not tinnitus perception or tinnitus distress is of uncertain clinical significance, may be spurious, and would need corroboration in additional studies. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive combined psychological and sound therapy, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus retraining therapy consists of a number of small randomized or quasi-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (Tinnitus Handicap Inventory scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuro-music therapy, a trial has used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. However, it is uncertain whether the multiple intensive interventions used in this trial could be replicated outside of the investigational setting. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive transcranial magnetic stimulation, the evidence includes a number of small- to moderate-sized RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from these studies are mixed, with some trials reporting a statistically significant effect of repetitive transcranial magnetic stimulation on tinnitus severity and others reporting no significant difference. Larger controlled trials with longer follow-up are needed for this common condition. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The available evidence does

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation. Moreover, while a 2017 meta-analysis found some benefit for transcranial direct current stimulation, it was noted that further study would be needed to evaluate transcranial direct current stimulation as a treatment option. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on electromagnetic energy includes a small RCT, which found no benefit for the treatment of tinnitus. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive transmeatal laser irradiation, the evidence includes RCTs and crossover trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence for transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no treatment efficacy. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

Supplemental Information

Practice Guidelines and Position Statements

International Federation of Clinical Neurophysiology

In 2017, the International Federation of Clinical Neurophysiology sponsored evidence-based guidelines on the use of transcranial direct current stimulation (tDCS). The guidelines did not recommend tDCS as a treatment for tinnitus because studies suggested anodal tDCS of the left temporoparietal cortex was probably ineffective (level B evidence). A lack of data precluded any recommendation on the use of tDCS of the left dorsolateral prefrontal cortex as therapy for chronic tinnitus.

American Academy of Otolaryngology – Head and Neck Surgeons

In 2014, the American Academy of Otolaryngology - Head and Neck Surgeons published evidence-based guidelines on tinnitus. Table 2 provides some of the Academy's recommendations.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Table 2. Guidelines on Treatment of Tinnitus

Recommendation	SOR	GOE
“Clinicians must differentiate patients with bothersome tinnitus from patients with nonbothersome tinnitus”	Strong recommendation	B
“Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussion about natural history and follow-up care”	Recommendation	B
“Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus”	Option	C
“Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus”	Recommendation	A
“Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus”	Recommendation against	B
“Clinicians should not recommend transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus”	Recommendation against	

GOE: grade of evidence; SOR: strength of recommendation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was retired in 2014.

Ongoing and Unpublished Clinical Trials

Some ongoing trials that might influence this review are listed in Table 3.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04004260	Cognitive Behavior Therapy Based Self-help Delivered Via the Internet for Tinnitus Sufferers: Efficacy Trial in the U.S. Population	158	Aug 2021
NCT04551404	Transcranial Electrical and Acoustic Stimulation for Tinnitus: A Randomized Double Blind Clinical Trial	40	Aug 2021
NCT03754127	A Randomized Controlled HD-tDCS Trial: Effects on Tinnitus Severity and Cognition	100	Sep 2022
NCT04661995	Notched Noise Therapy for Suppression of Tinnitus: A Randomized Controlled Trial	108	Dec 2026
Unpublished			
NCT01177137	Tinnitus Retraining Therapy Trial	151	Feb 2017 (completed)
NCT03022084	Clinical Trial of Sound-Based Versus Behavioral Therapy for Tinnitus	61	Jun 2019
NCT03114878	The Value of Eye Movement Desensitization Reprocessing in the Treatment of Tinnitus	166	Jan 2020 (completed)
NCT02438891	Evaluation of an Internet-based Sound and Cognitive Behavioral Therapy Course for Treatment for Tinnitus	200	Dec 2020 (completed)
NCT03511807	Acoustic and Electrical Stimulation for the Treatment of Tinnitus	100	Jan 2021 (status unknown)

NCT: national clinical trial.

^aDenotes industry-sponsored or co-sponsored trial.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Treatment of Tinnitus”, 8.01.39, March 2021.
2. Pichora-Fuller MK, Santaguida P, Hammill A, et al. Evaluation and Treatment of Tinnitus: Comparative Effectiveness (Comparative Effectiveness Review No. 122). Rockville, MD: Agency for Healthcare Research and Quality; 2013.
3. Hall DA, Hibbert A, Smith H, et al. One Size Does Not Fit All: Developing Common Standards for Outcomes in Early-Phase Clinical Trials of Sound-, Psychology-, and Pharmacology-Based Interventions for Chronic Subjective Tinnitus in Adults. *Trends Hear*. Jan-Dec 2019; 23: 2331216518824827. PMID 30803389
4. Jacquemin L, Mertens G, Van de Heyning P, et al. Sensitivity to change and convergent validity of the Tinnitus Functional Index (TFI) and the Tinnitus Questionnaire (TQ): Clinical and research perspectives. *Hear Res*. Oct 2019; 382: 107796. PMID 31514042
5. Fuller T, Cima R, Langguth B, et al. Cognitive behavioural therapy for tinnitus. *Cochrane Database Syst Rev*. Jan 08 2020; 1: CD012614. PMID 31912887
6. Landry EC, Sandoval XCR, Simeone CN, et al. Systematic Review and Network Meta-analysis of Cognitive and/or Behavioral Therapies (CBT) for Tinnitus. *Otol Neurotol*. Feb 2020; 41(2): 153-166. PMID 31743297
7. Sereda M, Xia J, El Refaie A, et al. Sound therapy (using amplification devices and/or sound generators) for tinnitus. *Cochrane Database Syst Rev*. Dec 27 2018; 12: CD013094. PMID 30589445
8. Jalilvand H, Pourbakht A, Haghani H. Hearing aid or tinnitus masker: which one is the best treatment for blast-induced tinnitus? The results of a long-term study on 974 patients. *Audiol Neurootol*. 2015; 20(3): 195-201. PMID 25924663
9. Davis PB, Wilde RA, Steed LG, et al. Treatment of tinnitus with a customized acoustic neural stimulus: a controlled clinical study. *Ear Nose Throat J*. Jun 2008; 87(6): 330-9. PMID 18561116
10. Hanley PJ, Davis PB, Paki B, et al. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice. *Ann Otol Rhinol Laryngol*. Nov 2008; 117(11): 791-9. PMID 19102123
11. Herraiz C, Diges I, Cobo P, et al. Auditory discrimination training for tinnitus treatment: the effect of different paradigms. *Eur Arch Otorhinolaryngol*. Jul 2010; 267(7): 1067-74. PMID 20044759

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

12. Okamoto H, Stracke H, Stoll W, et al. Listening to tailor-made notched music reduces tinnitus loudness and tinnitus-related auditory cortex activity. *Proc Natl Acad Sci U S A*. Jan 19 2010; 107(3): 1207-10. PMID 20080545
13. Stein A, Wunderlich R, Lau P, et al. Clinical trial on tonal tinnitus with tailor-made notched music training. *BMC Neurol*. Mar 17 2016; 16: 38. PMID 26987755
14. Li SA, Bao L, Chrostowski M. Investigating the Effects of a Personalized, Spectrally Altered Music-Based Sound Therapy on Treating Tinnitus: A Blinded, Randomized Controlled Trial. *Audiol Neurootol*. 2016; 21(5): 296-304. PMID 27838685
15. Hoare DJ, Kowalkowski VL, Kang S, et al. Systematic review and meta-analyses of randomized controlled trials examining tinnitus management. *Laryngoscope*. Jul 2011; 121(7): 1555-64. PMID 21671234
16. Westin VZ, Schulin M, Hesser H, et al. Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomised controlled trial. *Behav Res Ther*. Nov 2011; 49(11): 737-47. PMID 21864830
17. Bauer CA, Brozowski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: a controlled trial. *Ear Hear*. Mar-Apr 2011; 32(2): 145-55. PMID 20890204
18. Henry JA, Schechter MA, Zaugg TL, et al. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Otolaryngol Suppl*. Dec 2006; (556): 64-9. PMID 17114146
19. Phillips JS, McFerran D. Tinnitus Retraining Therapy (TRT) for tinnitus. *Cochrane Database Syst Rev*. Mar 17 2010; (3): CD007330. PMID 20238353
20. Grewal R, Spielmann PM, Jones SE, et al. Clinical efficacy of tinnitus retraining therapy and cognitive behavioural therapy in the treatment of subjective tinnitus: a systematic review. *J Laryngol Otol*. Dec 2014; 128(12): 1028-33. PMID 25417546
21. Argstatter H, Grapp M, Hutter E, et al. The effectiveness of neuro-music therapy according to the Heidelberg model compared to a single session of educational counseling as treatment for tinnitus: a controlled trial. *J Psychosom Res*. Mar 2015; 78(3): 285-92. PMID 25224125
22. Cima RF, Maes IH, Joore MA, et al. Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: a randomised controlled trial. *Lancet*. May 26 2012; 379(9830): 1951-9. PMID 22633033
23. Soleimani R, Jalali MM, Hasandokht T. Therapeutic impact of repetitive transcranial magnetic stimulation (rTMS) on tinnitus: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol*. Jul 2016; 273(7): 1663-75. PMID 25968009

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

24. Langguth B, Landgrebe M, Frank E, et al. Efficacy of different protocols of transcranial magnetic stimulation for the treatment of tinnitus: Pooled analysis of two randomized controlled studies. *World J Biol Psychiatry*. May 2014; 15(4): 276-85. PMID 22909265
25. Folmer RL, Theodoroff SM, Casiana L, et al. Repetitive Transcranial Magnetic Stimulation Treatment for Chronic Tinnitus: A Randomized Clinical Trial. *JAMA Otolaryngol Head Neck Surg*. Aug 2015; 141(8): 716-22. PMID 26181507
26. Song JJ, Vanneste S, Van de Heyning P, et al. Transcranial direct current stimulation in tinnitus patients: a systemic review and meta-analysis. *ScientificWorldJournal*. 2012; 2012: 427941. PMID 23133339
27. Pal N, Maire R, Stephan MA, et al. Transcranial Direct Current Stimulation for the Treatment of Chronic Tinnitus: A Randomized Controlled Study. *Brain Stimul*. Nov-Dec 2015; 8(6): 1101-7. PMID 26198363
28. Wang TC, Tyler RS, Chang TY, et al. Effect of Transcranial Direct Current Stimulation in Patients With Tinnitus: A Meta-Analysis and Systematic Review. *Ann Otol Rhinol Laryngol*. Feb 2018; 127(2): 79-88. PMID 29192507
29. Abtahi H, Okhovvat A, Heidari S, et al. Effect of transcranial direct current stimulation on short-term and long-term treatment of chronic tinnitus. *Am J Otolaryngol*. Mar 2018; 39(2): 94-96. PMID 29336898
30. Jacquemin L, Shekhawat GS, Van de Heyning P, et al. Effects of Electrical Stimulation in Tinnitus Patients: Conventional Versus High-Definition tDCS. *Neurorehabil Neural Repair*. Aug 2018; 32(8): 714-723. PMID 30019630
31. Byun YJ, Lee JA, Nguyen SA, et al. Transcutaneous Electrical Nerve Stimulation for Treatment of Tinnitus: A Systematic Review and Meta-analysis. *Otol Neurotol*. Aug 2020; 41(7): e767-e775. PMID 32472915
32. Deklerck AN, Marechal C, Perez Fernandez AM, et al. Invasive Neuromodulation as a Treatment for Tinnitus: A Systematic Review. *Neuromodulation*. Jun 2020; 23(4): 451-462. PMID 31524324
33. Dobie RA, Hoberg KE, Rees TS. Electrical tinnitus suppression: a double-blind crossover study. *Otolaryngol Head Neck Surg*. Oct 1986; 95(3 Pt 1): 319-23. PMID 3108780
34. Thedinger BS, Karlsen E, Schack SH. Treatment of tinnitus with electrical stimulation: an evaluation of the Audimax Theraband. *Laryngoscope*. Jan 1987; 97(1): 33-7. PMID 3491942
35. Mielczarek M, Olszewski J. Direct current stimulation of the ear in tinnitus treatment: a double-blind placebo-controlled study. *Eur Arch Otorhinolaryngol*. Jun 2014; 271(6): 1815-22. PMID 24337877

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

36. Ghossaini SN, Spitzer JB, Mackins CC, et al. High-frequency pulsed electromagnetic energy in tinnitus treatment. *Laryngoscope*. Mar 2004; 114(3): 495-500. PMID 15091224
37. Nakashima T, Ueda H, Misawa H, et al. Transmeatal low-power laser irradiation for tinnitus. *Otol Neurotol*. May 2002; 23(3): 296-300. PMID 11981384
38. Teggi R, Bellini C, Piccioni LO, et al. Transmeatal low-level laser therapy for chronic tinnitus with cochlear dysfunction. *Audiol Neurootol*. 2009; 14(2): 115-20. PMID 18843180
39. Ngao CF, Tan TS, Narayanan P, et al. The effectiveness of transmeatal low-power laser stimulation in treating tinnitus. *Eur Arch Otorhinolaryngol*. May 2014; 271(5): 975-80. PMID 23605244
40. Dehkordi MA, Einolghozati S, Ghasemi SM, et al. Effect of low-level laser therapy in the treatment of cochlear tinnitus: a double-blind, placebo-controlled study. *Ear Nose Throat J*. Jan 2015; 94(1): 32-6. PMID 25606834
41. Lefaucheur JP, Antal A, Ayache SS, et al. Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). *Clin Neurophysiol*. Jan 2017; 128(1): 56-92. PMID 27866120
42. Tunkel DE, Bauer CA, Sun GH, et al. Clinical practice guideline: tinnitus. *Otolaryngol Head Neck Surg*. Oct 2014; 151(2 Suppl): S1-S40. PMID 25273878
43. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Tinnitus Masking - RETIRED (50.6). 2014; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=85&ncdver=2&bc=AAAAGAAAAAAAAAA%3d%3d&>.

Policy History

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

09/11/2002 Medical Director review

09/18/2002 Managed Care Advisory Council approval

10/05/2004 Medical Director review

11/16/2004 Medical Policy Committee review

Format revision. Policy amended to include transmeatal irradiation as investigational.

11/29/2004 Managed Care Advisory Council approval.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Coverage eligibility updated. Additional techniques in the treatment of tinnitus are also considered investigational: Electromagnetic energy, transcranial magnetic stimulation and Botulinum toxin A.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. No change to coverage.
11/12/2009	Medical Policy Committee approval
11/18/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. New investigational indications added.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Transcranial direct current stimulation added to investigational statement.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

- 04/19/2017 Medical Policy Implementation Committee approval. Added coverage statement for psychological coping therapy for tinnitus and removed tinnitus retraining therapy, tinnitus coping therapy and botulinum toxin A injections from investigational statement.
- 04/05/2018 Medical Policy Committee review
- 04/18/2018 Medical Policy Implementation Committee approval. Biofeedback added to investigational list. Eligible for coverage statement changed to “Based on review of available data, the Company may consider psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be eligible for coverage.”
- 04/04/2019 Medical Policy Committee review
- 04/24/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/02/2020 Medical Policy Committee review
- 04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/01/2021 Medical Policy Committee review
- 04/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	97014, 97026, 97032
HCPCS	C1816, C1883, E0720, E0761, S8948
ICD-10 Diagnosis	H93.11-H93.19, H93.A1-H93.A9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Treatment of Tinnitus

Policy # 00127

Original Effective Date: 09/18/2002

Current Effective Date: 05/10/2021

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2021 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.